SEP - 8 2006

K060333

4.0 510(k) Summary of Safety and Effectiveness

4.1 Submitter: Dialysis Services, Inc.
130 Elder.
Springfield, TN 37172

4.2 Establishment Registration Number: 3004486997

4.3 Phone: (615) 384-4810

4.4 Fax: (615) 384-4847

4.5 Date Prepared: 02-06-2006

4.6 Contact Person: Mike Sterling

4.7 Device Names:

Trade Name:	*TYPHOON* Bicarb Mixing & Distribution System
Common Name:	Bicarb Mixing & Distribution System
Classification Name:	Hemodialysis Systems and Accessories (21 CFR 876.5820) Class II Critical Medical Device
Product Code:	78 FIP

4.8 Predicate Device: USFilter Bicarbonate Mixing and Dispensing System K031502

4.9 Device Description: Device is designed to provide the user with a system for consistent and easy to use system by which they may be able to mix and distribute bicarbonate solution for use in a hemodialysis clinic.

4.10 Intended Use: The TYPHOON by Dialysis Services, Inc. is intended to be used for the safe and effective mixing and distributing of a bicarbonate solution in a hemodialysis facility.

510(k) Summary

4.11 Predicate Device: The Dialysis Services Typhoon Bicarbonate Mixing and Distribution System and its components are substantially equivalent to the USFilter Bicarbonate Mixing and Dispensing System, K031502. Both the predicate device system and the Dialysis Services, Inc TYPHOON systems utilize similar technology. Further comparisons are made in the chart below.

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Technical Specifications and Information	Dialysis Services, Inc. TYPHOON	USFilter BICARB50SYS & BICARB100SYS
Requirements		
Inlet Water:	RO or DI water which meets AAMI standards for Hemodialysis	RO or DI water which meets AAMI standards for Hemodialysis
Drain:	Minimum of 1"	Minimum of 1"
Electrical:	115 vac, Single Phase, 20 amp	115 vac, Single Phase, 20 amp
Piping:		
Water Inlet:	1" schedule 80 PVC	½" schedule 80 PVC
Loop Feed:	¾" schedule 80 PVC, or 5/8" polyethylene	¾" schedule 80 PVC
Loop Return:	¾" schedule 80 PVC, or 5/8" polyethylene	¾" schedule 80 PVC
Drain:	1 ½" schedule 80 PVC	1" schedule 80 PVC
Level Controls:		
Mix Tank Level Control:	The Dialysis Services TYPHOON gives the user the ability to mix and distribute from both tanks, so there is not a separate Mix and Distribution tank. Because of this, both tanks utilize the same level control sensor and operate the same. The sensor automatically allows the system to fill in 50 gal., 75 gal., and 100 gal. increments (user selected). The level sensor controls the fill valve with these levels. In addition, when the bicarbonate level drops to 10 gallons in the tank being used, it will give an audible and visual alarm and/or automatically switch tanks. (See Operator's Manual for details)	The mix tank is equipped with a high level float that closes the fill valve if the water in the tank exceeds 100 gals. (50 gals. for a 50 gal. system). The fill valve will not reactivate unless the water level is below float level.
Distribution Tank Level Control:		The distribution tank is equipped with a low-level float that lights a warning light if the bicarbonate in the tank drops below 25 gals. if the distribution tank is allowed to go empty, and audible alarm will sound.

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Technical Specifications and Information	Dialysis Services, Inc. TYPHOON	USFilter BICARB50SYS & BI-CARB100SYS
Pumps:		
Mix Pump:	1/3 hp Totally Enclosed Fan Cooled (TEFC) motor	3/4 hp Totally Enclosed Fan Cooled (TEFC) motor
Distribution Pumps:	1/4 hp Totally Enclosed Fan Cooled (TEFC) motor	1/9 hp Totally Enclosed Fan Cooled (TEFC) motor
Material		
Tank Materials:	Polyethylene	Polyethylene

510(k) Summary

4.12 Non-Clinical Performance Data:

The Dialysis Services, Inc. TYPHOON Bicarb Mixing and Distribution System utilizes similar components and fluid contact materials as other items currently cleared for use in hemodialysis

4.13 Clinical Testing:

N/A

4.14 Biocompatibility Testing:

Dialysis Services, Inc. certifies that most materials and components utilized in the TYPHOON Bicarb System are identical to those previously cleared and registered with the FDA. Additional testing is provided in Section 9.0 of this submission.

4.15 Conclusions:

As with the USFilter Bicarbonate Mixing and Distribution System, the Dialysis Services, Inc, TYPHOON Bicarbonate Mixing and Distribution System is intended to consistently mix and distribute bicarbonate solution for use in hemodialysis.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 8 2006

Mr. Mike Sterling
VP/COO
Dialysis Services, Inc.
3620 Kelton Jackson Road
SPRINGFIELD TN 37172

Re: K060333
Trade/Device Name: Dialysis Services, Inc. TYPHOON Bicarb Mixing and Distribution System
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIN
Dated: August 23, 2006
Received: August 24, 2006

Dear Mr. Sterling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060333

Device Name: Dialysis Services, Inc. TYPHOON Bicarb Mixing and Distribution System

Indications For Use:

The bicarbonate mixing and distribution system and its components consisting of; tanks, pumps, piping, and controls, are designed to consistently, safely, and effectively mix and distribute bicarbonate solutions for hemodialysis treatments.

NOTE: Federal Law restricts this device to sale by or on the order of a physician for use as a bicarbonate mixing and distribution system for hemodialysis.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060333

(vers 6/25/05)